

REMARKS

Claims 23-76 are pending. Claims 36, 37, 39, 40 and 48 have been canceled. Claims 23, 24, 26, 27, 41, 42, 43, 44, 49, 50 and 52 have been amended. Claims 77 and 78 have been added. No new matter has been added by virtue of the amendments, support therefore being found throughout the originally filed specification.

1. 35 U.S.C. §112 Rejection

Claims 23 and 60 were rejected under 35 U.S.C. §112, second paragraph. In particular, the Office asserted that the claims use the term "the device" but that there is no limitation in the claim that describes the device. Applicants respectfully traverse.

Claim 23 reads as follows (emphasis added):

23. A method for treating an eye comprising:
inserting into an eye **a device comprising a piercing member and a cannula slidably disposed within the piercing member**, wherein the step of inserting the device into the eye comprises piercing the sclera of the eye with the piercing member and advancing the piercing member transconjunctivally through the sclera of the eye;
advancing the cannula through the piercing member towards a treatment site; and
treating the eye.

Applicants respectfully submit that claim 23, as written, clearly sets forth elements describing the device. In particular, claim 23 states that the device comprises a piercing member and a cannula insertable within the piercing member. Thus, claim 23 claims a method wherein the device comprises both the piercing member and the cannula.

Claim 60 reads as follows (emphasis added):

60. A method for treating an eye comprising:
inserting into an eye **a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member,**

wherein the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye;
advancing the cannula through the outer member and beyond the distal end into the eye; and
treating the eye

Applicants respectfully submit that claim 60, as written, clearly sets forth elements describing the device. In particular, claim 60 states that the device comprises an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member.

Applicants respectfully request reconsideration and withdrawal of the rejection.

2. 35 U.S.C. §102 Rejection

Claims 23-30, 32, 33-40, 42-44, 47-52, 54, 55, 58-65, 67-69 and 72-76 have been rejected under 35 U.S.C. §102(e) as being anticipated by Paques et al. (US Pub 2003/0171722). Applicants respectfully traverse the rejection.

Applicants' claim, in independent claim 23, a method for treating an eye comprising inserting into an eye a device comprising a piercing member and a cannula slidably disposed within the piercing member. In particular, the step of inserting the device into the eye comprises piercing the sclera of the eye with the piercing member and advancing the piercing member transconjunctivally through the sclera of the eye. The cannula is then advanced through the piercing member towards a treatment site and the eye is treated.

Paques, on the other hand, describes an instrument that has a handpiece 2 carrying a hollow needle 4 sharpened at its tip. The handpiece has a passageway 6 for delivering substance through the device. The handpiece may also have a second passageway 12 for receiving an optical fiber 14. According to Paques' method "The instrument of Figs. 1-3 is used to **introduce**

the needle 4 and the distal end 14d of the optical fiber 14 into the eye through a sclerotomy" ([0048] line 3-6). "The **retinal vein** is then **penetrated with the sharp distal end of the needle 4**" ([0048] line 12-13, emphasis added). Again, at [0052], line 3-6, Paques states that "The **retinal vein is penetrated upstream * * * by the sharp end of the hollow needle 4 * * ***". At [0077] line 6-8, "a hollow miniaturized **needle** sharpened at its tip **for penetrating the blood vessel in the subject's retina**".

Thus, Paques describes a method wherein (1) a sclerotomy (surgical incision) is made in the eye, (2) a device comprising a handpiece with a sharpened needle is introduced into the eye through the sclerotomy, (3) the sharpened needle is advanced with the remainder of the device into the eye and (4) the sharpened needle pierces a blood vessel in the eye. Paques clearly does **not** describe or suggest Applicants' claimed method which comprises (1) piercing the sclera of the eye with a piercing member and advancing the piercing member transconjunctivally through the sclera of the eye, (2) advancing a cannula through the piercing member towards a treatment site and (3) treating the eye.

Accordingly, claim 23 is not anticipated by Paques. Claims 24-26, 38, 41-47 and 74 depend from claim 23 and, likewise are not anticipated by Paques. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in independent claim 27, a method of treating an eye, comprising: piercing the eye with a piercing member and inserting the piercing member into the vitreous humor of the eye, the piercing member having a proximal end and a distal end and a lumen defined therebetween; advancing a cannula through the piercing member lumen and beyond the distal end of the piercing member; guiding the cannula through the vitreous humor of the eye to a treatment site; and treating the treatment site.

Thus, like claim 23, Applicants' method comprises piercing the eye with a piercing member and inserting the piercing member into the eye followed by advancing a cannula through and beyond the piercing member. In particular, the cannula is guided through the vitreous humor to a treatment site. The treatment site is then treated.

As set forth above, Paques does **not** describe or suggest a method wherein a piercing member pierces the eye and is inserted into the eye as set forth in claim 27. Paques further does not describe or suggest advancing a cannula through and beyond the piercing member into the eye to a treatment site as set forth in claim 27. Rather, Paques merely describes a method wherein a sclerotomy is made in the eye followed by insertion of a handpiece with a sharpened needle through the sclerotomy into the eye. The handpiece and needle are guided to a blood vessel in the eye, and the needle is used to pierce the blood vessel.

Accordingly claim 27 is not anticipated by Paques. Claims 28-35, 49-59 and 75 depend from claim 27 and, likewise, are not anticipated by Paques. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants claim, in independent claim 60, a method for treating an eye comprising: inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing member at the distal end of the outer member. In particular, the step of inserting the device into the eye comprises piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye. The method further comprises advancing the cannula through the outer member and beyond the distal end into the eye and treating the eye.

As set forth above, Paques does **not** describe or suggest such a method. Paques does **not** describe or suggest inserting into an eye a device comprising an outer member having a proximal end and a distal end, a cannula slidably disposed within the outer member, and a piercing

member at the distal end of the outer member. In particular, Paques does not describe inserting the device into the eye by piercing the eye with the piercing member and advancing the piercing member and at least a portion of the outer member into the eye, followed by advancing the cannula through the outer member and beyond the distal end into the eye and treating the eye.

Accordingly, claim 60 is not anticipated by Paques. Claims 61-73 and 76 depend from claim 60 and, likewise are not anticipated by Paques.

2. 35 U.S.C. §103 Rejections

Claims 31, 45, 46, 56, 57, 70 and 71 have been rejected under 35 U.S.C §103(a) over Paques et al. (U.S. Patent Application 2003/0171722) in view of del Cerro et al. (U.S. Patent 5,409,457).

Applicants respectfully submit that independent claims 23, 27 and 60 (the only pending independent claims) are patentable over Paques for the reasons set forth above. In particular, a prima facie case of obviousness cannot be made because Paques does not teach or suggest each and every claim limitation. Further, there is absolutely **no** suggestion or motivation to modify Paques as required by Applicants' claims. Paques exclusively describes methods wherein a device is inserted into the eye through a surgical incision. Further, Paques exclusively describes methods wherein a sharpened needle pierces a **blood vessel in the eye** after the sharpened needle, along with the remainder of the device have been inserted into the eye through the surgical incision. There is no description or suggestion that the sharpened needle should or could be used to pierce the eye to provide an opening through which the entire device (which is larger in diameter than the sharpened needle, which forms only a portion of the device's profile) could be inserted into the eye. This description comes purely from Applicants' disclosure.

Further, del Cerro, if it could be properly combined with Paques, which Applicants submit it cannot, still would not teach or suggest Applicants' methods. In particular, del Cerro,

like Paques, does not describe a method wherein the eye is pierced with a piercing member, the piercing member advanced into the eye, advancing a cannula through and beyond the piercing member into the eye towards a treatment site, and treating the eye. This comes purely from Applicants' disclosure. Applicants further note that del Cerro specifically *teaches against* a transcleral approach, which is the approach that Applicants use in their methods.

Accordingly, claims 23, 27 and 60 are patentable over Paques in view of del Cerro. Claims 24-26, 28-35, 38, 41-47, and 49-59 and 61-78 depend from claims 23, 27 and 60 and, likewise are patentable over Paques in view of del Cerro. Reconsideration and withdrawal of the rejection is respectfully requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

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Respectfully submitted,



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